REMARKS

The last Official Action in the above-identified application has been carefully considered. The Examiner's indications that claims 18-24 are allowed and claim 14 would be allowable if rewritten in independent form are greatly appreciated. This amendment has been presented to place this application in condition for allowance. Accordingly, reexamination and reconsideration of this application are respectfully requested.

By this amendment, minor corrections have been made to page 7 of the specification changing the term "body 10" to --implant 10--. Claim 1, 11 and 15 have been amended. Claim 4 has been cancelled, without prejudice, to its subsequent prosecution in any continuing application or disclaimer of any of the proprietary rights set forth therein. Claims 1-3 and 5-24 remain pending in the application.

In the Official Action, claims 1, 2 and 5-7 have been rejected under 35 U.S.C. §102(b) as being anticipated by Härle (U.S Patent 5,769,897). Härle teaches an artificial bone material made up of a strength sustaining first component and of a biointegration promoting second component. The first component can be of hydroxyapatite, provided that it has a strength of at least 1000 N/cm^2. The first component has a plurality of relatively large accessible voids with dimensions in the range of 1-5mm, ie 1000-5000μm (column 6, lines 22-23). The second component can be of tricalcium phosphate provided that it has open micropores having dimensions within the range of 10-300μm (column 6, line 25). The second component is located inside the accessible voids in the first component (column 6, lines 35-36). As can clearly be seen in Figures 1-10 of Härle, the accessible voids are deliberately and specifically formed in the first component, ie they (and hence the second component) are located at predetermined positions in the first component. In contrast, in the present invention, the zones of resorbable bioactive material are randomly dispersed throughout the body of

non-resorbable bioactive material, as claimed in Claim 1. In other words, in the implant of Claim 1, the positioning of the zones of resorbable bioactive material lacks any definite plan or prearranged order, i.e. the zones are haphazardly arranged in contrast to the prearranged or predetermined order of the accessible voids in the first component of Härle.

This also applies to the implant of Figures 11 to 13 of Härle. In Figures 11 to 13, the first component forms a skeletal supporting structure that is either a honeycomb structure or a tubular structure (column 8, lines 31-32). An open cellular structure is thus provided and, again, the accessible voids 1d in which the second component is located have a prearranged or predetermined order, i.e. they are not randomly or haphazardly arranged within the first component.

Additionally, applicants respectfully submit that the Examiner is incorrect in asserting that, in Härle, the zones of tricalcium phosphate are from 0.3-3mm, i.e. 300 to 3000μm, in size, that they are in a size range which overlaps the size range of 10 to 500μm specified in Claim 1. Härle clearly teaches that the second biomaterial, e.g. the tricalcium phosphate, is located in accessible voids in the first component, with the accessible voids having dimensions in the range of 1-5mm, i.e. 1000-5000μm (column 6, lines 22-23 and column 8, lines 42-45). The second material, the tricalcium phosphate, can initially be in the form of granules which are in the size range 0.3-3mm. However, clearly the zones of tricalcium phosphates are not 0.3-3mm in size since each of the zones, that is, the accessible voids of 1-5mm, will contain a plurality of the granules.

An unexpected advantage that the implant of Claim 1 has is that it has both osteoconductive and osteoinductive properties. Furthermore, the implant of Claim 1 has high bioactivity with partial controllable resorbability. When there has been complete resorption of all of the resorbable bioactive material from the zones containing this material, a skeleton or scaffold of hydroxyapatite,

containing a random arrangement of openings where bone growth can take place, remains. See page 9, lines 16-33 of the present specification.

Since claims 2 and 5 to 7 depend from Claim 1, which is both novel and non-obvious over Härle, these claims are also thus believed to be allowable therewith.

Based upon the foregoing, it is believed that the Examiner's rejection of claims 1, 2 and 5-7 based upon 35 U.S.C. §102(b) has been overcome by the present amendment and remarks and withdrawal thereof is respectfully requested.

In the Official Action, claims 3-4, 8-13, and 15-17 have been rejected under 35 U.S.C. §103 as being unpatentable over Härle. Since each of the claims 3-4, 8-13 and 15-17 are ultimately dependent upon claim 1, it is believed that these claims are patentably distinguishable from Härle for those reasons discussed above.

In any event, as regards claim 3, by having all the zones of tricalcium phosphate of the same size, osteoinduction is enhanced since, in use, such zones yield pores on resorption that encourage further osteoinduction. Härle is totally silent on providing an implant that is both osteoconductive and osteoinductive.

As regards Claim 4, the major concept thereof, namely that the zones of tricalcium phosphate are randomly dispersed throughout the hydroxyapatite body, has been incorporated into Claim 1. Claim 4 has thus been cancelled, without prejudice.

As regards Claims 8 and 9, it is respectfully submitted that the feature of the macropores being substantially spherical and being interconnected by being coalesced together, is not merely "one of numerous shapes or configuration a person of ordinary skill in the art would find obvious for the purpose of providing pores in an implant". By providing macropores that are substantially spherical and which are interconnected by being coalesced together, osteoinductivity is promoted.

For example, rounded macropores which are connected together by being coalesced together rather than by narrower diameter passages, enhances osteoinductivity - this is not at all taught or suggested in Härle.

Similarly, in respect to Claim 10, the statement that "where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art" does not apply. As emerges also from page 9, lines 11 to 15, when the implant has a final macroporous volume in this range, it is ensured that a bone implant having both osteoconductivity and osteoinductivity is obtained.

The same comments as have been made for Claims 8, 9 and 10, apply in respect of Claim 11.

Regarding Claims 12 and 13, the surface concavities of Buschel (US 5868796) are biologically inert, and are provided for biological fixation through physical means.

In contrast, the surface concavities of Claims 12 and 13 are provided in a bioactive surface and are rounded, in order to enhance osteoinduction. Buechel is also totally silent as regards osteoinduction.

As regards the micropores, Claim 15 clearly specifies that the micropores are randomly interspersed throughout the body of non-resorbable material (hydroxyapatite) as well as throughout the zones of resorbable material (tricalcium phosphate). In contrast, in Härle, the micropores are provided in the tricalcium phosphate material only -see, for example, column 8, lines 45 to 53. In fact, Härle teaches away from providing any porosity in the first component, i.e. in the hydroxyapatite, in order to preserve the strength thereof - see column 8, lines 56 to 67 thereof.

For all of the foregoing reasons, it is believed that the Examiner's rejections of claims 3-4, 8-13 and 15-17 under 35 U.S.C.§103(a) have been overcome by the present amendment and remarks and withdrawal thereof is respectfully requested.

In view of the foregoing amendment and remarks, it is respectfully submitted that the application as now presented is in condition for allowance. Early and favorable reconsideration of the application are respectfully requested.

Statements appearing above in respect to the disclosures in the cited references represent the present opinions of the undersigned attorneys and, in the event that the Examiner disagrees with any of such opinions, it is respectfully requested that the Examiner indicate those portions of the respective references providing the basis for a contrary view.

An additional fee of $420.00 is deemed to be required for a two (2) month extension of time for the filing of this amendment. Please charge any additional fee or credit any overpayment for this application to Deposit Account No. 50-0320.

A Notice of Allowance is earnestly solicited.

Respectfully submitted,

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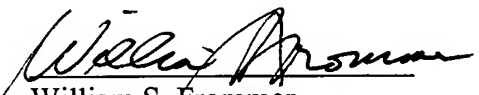
By: 
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